



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,776	12/17/2004	Hideaki Sasagawa	TOYA107.005APC	5644

20995 7590 12/24/2008
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
----------	--------------

1614

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

12/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/518,776	Applicant(s) SASAGAWA ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/17/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-18 are presented for examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign

Art Unit: 1614

document and are replete with grammatical and idiomatic errors. Specifically, with regard to claim 14, it is unclear what is meant by the terms "wherein the coating film having plastic property shows a glass state having viscosity". Clarification is required.

Regarding claim 16, the word "means" is preceded by the word "swelling" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). Further, the same claim recites the phrase "means for physical scratching". The claim meaning is indeterminate because there is nothing in the claim elements to support the performance of the specified function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1614

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al. WO 97/02821 A2 and JP 7 277975 (machine translation provided) and Sawyer U.S. Patent No. 6,403,063 B1.

The claims are drawn to a pharmaceutical composition comprising the antifungal agent of figures (1) and (2) combined with (A) a film forming agent selected from *inter alia*, ethyl cellulose and (B) a water soluble plasticizer in a form of a solid or a paste at 20°C (68°F or approximately normal room temperature) at 1 atm (normal atmospheric pressure) selected from a polymer or copolymer of oxyethylene and/or oxypropylene and has a polymerization degree of 70 or more.

JP 7 277975 teach an antifungal formulation comprising film forming agents selected from ethyl cellulose and hydroxypropylcellulose phthalate combined with plasticizers (see claim 1, page 1).

Art Unit: 1614

JP 7 277975 does not teach the specific antifungal agents and the specific plasticizers.

Kodama et al. teach the antifungal agents in figures (1) and (2) (see entire document). It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezei* 158 USPQ 99; the express suggestion to substitute the antifungal composition of Kodama et al. for the antifungal of JP 7 277975 need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

Regarding the plasticizers recited, Sawyer teaches the composition for treating nail fungus comprising an antifungal agent and a plasticizer (column 20, line 50). The plasticizer agent, oxyethylene oxypropylene copolymer is recited (column 13, line 39). The reaction mixture treats onychomycosis (columns 1-2) (mycosis of the nails resulting in thickened nails) by penetrating the thickened nail (addressing the limitations of instant claim 17) to polymerize to form a polyurea therapeutic coat on the treated nail (column 16, line 59 to column 17, line 7). The film or coat is solid at room temperature and at normal atmospheric pressure. Addressing claims 9-11, wetting agents are disclosed (surfactants) such as the alkyl sulfate, anionic, surfactant, sodium dioctyl sulfosuccinate (column 25, lines 55-67). Addressing instant claim 15 wherein the antifungal medicinal composition is capable of recoating, Sawyer teaches that the stabilized reaction solution is applied to the nail topically *to form a liquid film of a desired thickness* (column 22, lines 25-27).

Art Unit: 1614

The medicinal antifungal coating composition having a plastic property when applied to the target (medicinal nail polish) is known in the art by the teachings of Sawyer and film forming topical agent as disclosed in JP7 277975.

One of ordinary skill in the art could have substituted the antifungal agent of Sawyer and JP7 277975 for the antifungal agents of Kodama et al, and the results of the substitution would have been predictable. It would have been prima facie obvious to substitute the antifungal agent of Kodama for the antifungal agent of either Sawyer or JP7 277975. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious.

The prior art showed that onychomycosis is successfully treated with a film forming antifungal agent with a plasticizer and film forming agent and further comprising a surfactant. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the antifungal agents taught in Kodama et al for the antifungals of JP7 277975 or Sawyer for the predictable result of forming an antifungal medication that forms a film on the affected area so that it does not wash away easily. Addressing the limitations of instant claim 18, drawn to the method of producing an antifungal medicinal composition, "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art,

Art Unit: 1614

although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

December 11, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614